



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61M 31/00	A1	(11) International Publication Number: WO 90/07353
		(43) International Publication Date: 12 July 1990 (12.07.90)

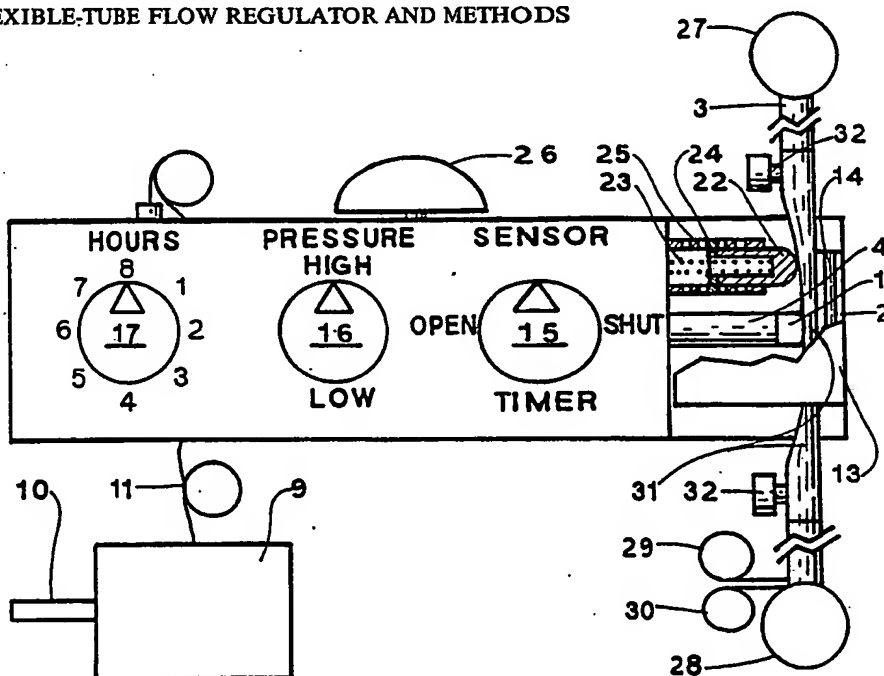
(21) International Application Number: **PCT/US89/00010**(22) International Filing Date: **3 January 1989 (03.01.89)**(71) Applicant (for all designated States except US): **MEDICAL INVENTORS CORP. [US/US]; 7575 DR. Phillips Blvd., Suite 310, Orlando, FL 32819 (US).**

(72) Inventor; and

(75) Inventor/Applicant (for US only): **FLINCHBAUGH, David, Edward [US/US]; 4855 Big Oaks Lane, Orlando, FL 32806 (US).**(74) Common Representative: **FLINCHBAUGH, David, E.; 4855 Big Oaks Lane, Orlando, FL 32806 (US).**(81) Designated States: **AT (European patent), AU, BB, BE (European patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH (European patent), CM (OAPI patent), DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB (European patent), HU, IT (European patent), JP, KP, KR, LK, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL (European patent), NO, RO, SD, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.****Published***With international search report.*(54) Title: **PROGRAMMABLE FLEXIBLE-TUBE FLOW REGULATOR AND METHODS**

(57) Abstract

Flow regulation for flexible tubes is provided by pressing the opposite sides of a tube (3) or a tubular section together to close or to selectively open the tube programmably thereby with electrically-motorized members. It is a form of valve that does not require flow of fluid through a valve-operating mechanism. A medical, hospital and home-care unit for bladder cycling of patients is provided with a pressure transducer (22) that opens and closes the valve in accordance with programmed pressure or time intervals. A medication infusion system that can be implantable is provided by regulating flow of fluid from a medication reservoir (27) into the blood or digestive system of patients (28) with appropriate electrochemical transducers and with appropriate medication reservoir and tubing. Industrial and consumer applications can be provided with appropriately designed size and construction modifications.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MR	Mauritania
BE	Belgium	GA	Gabon	MW	Malawi
BF	Burkina Faso	GB	United Kingdom	NL	Netherlands
BG	Bulgaria	HU	Hungary	NO	Norway
BJ	Benin	IT	Italy	RO	Romania
BR	Brazil	JP	Japan	SD	Sudan
CA	Canada	KP	Democratic People's Republic of Korea	SE	Sweden
CF	Central African Republic	KR	Republic of Korea	SN	Senegal
CG	Congo	LI	Liechtenstein	SU	Soviet Union
CH	Switzerland	LK	Sri Lanka	TD	Chad
CM	Cameroon	LU	Luxembourg	TG	Togo
DE	Germany, Federal Republic of	MC	Monaco	US	United States of America
DK	Denmark				

--Programmable Flexible-Tube Flow Regulator and Methods--

5 Field of the Invention.

 This invention relates to hospital, clinical or home-care medical
instruments. In one of its embodiments, it is a programmable, pressure-
transducer-controlled bladder-drainage cyclor. In another of its embodiments,
it is a programmable, electrochemical-transducer-controlled medication
10 infusion system that can be made to be implantable or operable from outside
the body of a patient. More generally, it is a flow regulator for regulating
flow of fluid through a flexible tube for a broad range of industrial and
consumer applications.

 Description of related art.

15 In relation to bladder cycling, hospital instruments and procedures for
draining bladders of patients have evolved from constant uncycled drainage
through siphoning, suction and various types of cyclic methods. Fundamental
to an effective instrument and method is allowing the bladder to fill
reasonably and then draining it without a suction effect and without allowing
20 build-up or entry of infectious contaminants in the drainage system. Aspects
to be avoided in bladder cycling are constant drainage, excessive negative
pressure and incomplete drainage of either the bladder or the catheter
equipment used.

 Described in U.S. Patent Application, Serial Number 238,484, filed
25 08/31/88 by the same inventor, Dr. David E. Flinchbaugh, is a magnetic bladder
cyclor and use method. The magnetic bladder cyclor provided greater accuracy
and reliability in filling the needs of an effective bladder cyclor in
comparison to prior devices. It was not fully programmable, however. Nor did
it permit the control of fluid through a medical tube without flow also
30 through the control mechanism. Flow of fluid through the control mechanism
required the use of a new mechanism for each new patient and periodically, a
new mechanism for the same patient to minimize contamination.

 This invention, however, allows repeated use of the same control
mechanism for different patients. Only the medical tubing needs changing to
35 avoid contamination. The control unit can have a long use-life at low cost
for a medical tube system without contamination. Further, it is programmable
for total control to meet the needs of each patient completely.

For infusion of medication into the body of patients, there is currently a programmable medication infusion system. It is implantable in the body as described in U.S. Patent Number 4,373,527. However, it controls flow through valves and components of a control mechanism rather than more simply and accurately through only a tube.

In addition to controlling infusion of medication more accurately and reliably, flow control through a tube decreases contamination by avoiding the many crevices for growth of contamination in and around the components of control mechanisms. Highly significant also, the tube can be replaced easily at minimal costs in comparison to difficult and expensive replacement of present programmable medication infusion mechanisms when they have become inoperable or contaminated.

Further, this invention does not require changing as often because it avoids contamination for which changing would be required and its components are longer-lasting and more reliable.

Long use-life, high reliability and greater accuracy of this invention for medication infusion and for bladder cycling result from simplicity of its components. Medication can be supplied in either a continuous small stream or in doses as required. Requirements for medication can be determined by electrochemical transducers to assure proper dosage and to prevent overdose hazards. Bladders can be cycled completely without hazardous suction. The medical tubing used can be collapsible to avoid contamination.

A major feature of this invention is that in all medical uses, its fluid-flow-control mechanism is most nearly like the natural flow control of fluids by muscular contraction and expansion in a living body. Thus, it is more appropriate and compatible for use by the body.

The type of programming to which this invention is suited for most purposes is basically analog as contrasted to digital programming. This approximates body functions as well as most requirements of flow regulation.

Smallness in size is critical for implantation of medication infusion systems. This invention can be made much smaller than present control systems because it is simpler in construction and there are fewer parts.

Included in previous devices for bladder cycling have been U.S. Patent Numbers 2,602,448 and 2,860,636 which utilized a siphon in combination with a reservoir to provide cyclic draining of the bladder. Pressure release in these is controlled by raising the height of the device on a bedside tree. It is subject to distortion by shifting and turning of the patient and,

therefore, very undependable in addition to being restrictive of the patient.

In U.S. Patent Number 3,598,124, a siphon leg is controlled by merely attaching a catheter to a bedside tree at predetermined adjusted height, which varies the pressure at which the bladder will drain and provides a flutter valve near the patient to break the siphon action of the system once the bladder has drained. In U.S. Patent Number 4,230,102, a device for the draining of a bladder is shown in which a T-joint has been placed on a catheter and has a pressure membrane attached thereto in a large casing for actuating a pressure switch which in turn actuates an electric motor driving a gear train and cam. A cam follower is spring loaded to close the catheter for two-minute cycles upon actuation by the pressure switch to drain the bladder. This type of device, however, is expensive and bulky. In U.S. Patent Number 4,424,058, a spring-return valve is provided in conjunction with a siphon-release orifice to prevent excessive suction and to prevent urine from remaining in the system after drainage. A problem with that system was that resistance of the spring increased with distance of travel from a closed position. This tended to cause some fluid to remain in the bladder because only a full bladder would open it and only a relatively full bladder would keep it open sufficiently to allow complete drainage unless overridden by the patient. Also, positioning of tubes leading from it were parallel to the leg on which it was attached and provided a situation for retention of fluid in the system.

SUMMARY OF THE INVENTION

In this invention, flow of fluid through a flexible tube is stopped, allowed or regulated in amount by programmable pressing of the sides of the flexible tube together selectively. For hospital and other medical applications, the flexible tube can be a catheter tube for cycling a bladder or an infusion tube for infusing medication into the blood stream or for infusing medication into the digestive tract. The flow through such tubes can be programmable for control by a pressure transducer, by a chemical transducer, by an electrochemical transducer or by a timer. Either can be made to be overridden manually.

Applications of this invention for cycling bladders and for infusing medication differ primarily in whether input or output of fluid is being controlled. The types of flexible tubing utilized and the types of transducers utilized for programmable control also can be different. When used as a bladder cycler, the inlet tube utilized is a catheter because the source

of fluid is the bladder. When used as medication infuser, the inlet tube is a medication tube because the source of fluid is a medication reservoir. The outlet tube is an excretion discharge conveyance when this invention is employed as a bladder cyclor. When employed as a medication infuser, the outlet tube is a medication infusion tube that is attachable selectively to either the blood system or the digestive tract of a patient.

The programmable control principles and mechanisms for both applications are substantially the same except that flow regulation is controlled programmably by a pressure transducer for a bladder cyclor and by electrochemical transducers for medication infusion. Both are programmable also for timed valved closing, opening and variable flow regulation. Also, both are provided with manual override.

With appropriate modification but with substantially the same basic principles, the medication infuser can be miniaturized for implantation into the body of the patient. Partly because it is simple and yet basically free from contamination in operation, it can be made smaller and more reliable than other implantable, programmable medication infusion systems.

In this invention, a controllable-step motor, preferably a linear motor, is utilized to actuate a rod against a flexible tube supported by a base member at the opposite side of the tube in order to prevent or to selectively allow flow of fluid through the tube. When used as a bladder cyclor, a pressure sensor at an inlet side of the rod and base member senses radially outward pressure in the tube and actuates a switch to activate the linear motor as programmed. When used as a medication infuser, either a chemical transducer, an electrical transducer or both can be employed. Fluid flow of medication through infusion tubes to the blood system or to the digestive tract of patients can be programmed as required.

The controllable-step motor can also be rotational with gear drive of a rod which functions as a valve to open and close the tube for selective regulation of flow of fluid. A variety of mechanisms are described for programmable flow control through a flexible tube within this invention.

When used for various industrial and consumer applications, the size of the components can be adjusted to the particular needs.

Miniaturization of the invention for such applications as implantable, programmable medication infusion systems can be aided by the use of collapsible tubes to decrease the energy required to operate the linear valve and thereby to decrease the size of the unit.

5

Collapsible tubes also decrease contamination by decreasing fluid remaining within the tubes when not otherwise conveying fluid. This further decreases stagnation conditions in the system.

DESCRIPTION OF DRAWINGS

5 FIG 1 is a cutaway side view of a bladder-cycler embodiment of the invention employing a linear motor in direct actuation of a flexible-tube flow regulator .

FIG 2 is a top view of the embodiment illustrated in FIG 1.

10 FIG 3 is a top view of a medication-infusion embodiment of the invention utilizing a linear motor similarly to the FIG 1 illustration.

FIG 4 is a schematic side view with a rotational electrically-motorized means in conjunction with an inclined plane.

FIG 5 is a schematic side view with a linear electrically-motorized means in conjunction with an inclined plane.

15 FIG 6 is a schematic side view with a linear electrically-motorized means to actuate a plier-like lever and fulcrum.

FIG 7 is a flow diagram of a bladder-cycler embodiment of the invention.

FIG 8 is a flow diagram of a medication-infusion embodiment of the invention.

20 FIG 9 is a circuit diagram of the invention illustrating circuitry for bladder-cycler, medication-infusion and other applications.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring to FIG 1, a contractible member 1 is actuated selectively in the direction of or in the opposite direction from a base member 2 to regulate
25 flow of fluid through a flexible tube 3. Motion for actuation of the contractible member 1 is transferred through motive member 4 from plunger 5 which can be a conductor in a linear motor having electrical coils 6 in a linear electrical step motor 7. The linear step motor can also be a rotational motor, preferably a rotational step motor, that operates gears.
30 Because either a linear motor or a rotational motor with gears can be employed, an electrical motor of either type is referred to alternatively in this description as an electromotive means. Contractible member 1 and base member 2 can be referred to together as a regulator valve which is opened fully or partially by movement of contractible member 1 selectively in a
35 direction away from base member 2. It is closed by movement of contractible member 1 in a direction towards base member 2 to press opposite sides of a flexible tube 3 together with sufficient force to prevent flow of fluid

6

through the tube 3.

Electrical current is provided to the electrical coils 6 by battery 8 which can be chargeable. Electrical current for charging battery 8 is supplied from battery charge box 9 having electrical plug 10. Low voltage current is transmitted through charger wire 11 to converter 12. The converter 12 can be a converter of relatively high voltage to relatively lower voltage within a low-voltage system. The battery charge box 9 is employed to isolate high current of an electrical source from low current in association with a patient or other use condition. This prevents electrical hazards in addition to providing efficient charging of a battery.

An optional tube cover 13 is swivelable on hinge bolt 14 to prevent the flexible tube 3 from escaping from between the contractible member 1 and the base member 2 under use conditions.

Referring now to both FIG 1 and FIG 2, a regulator knob 15 is rotatable in either direction to select the programmable regime. At the position designated "SENSOR" at a 12 O'clock position, the program selected is for closing of contractible member 1 and opening it in accordance with pressure in flexible tube 3. The amount of pressure required to open the regulator valve by movement of contractible member 1 away from base member 2 and flexible tube 3 is determined by rotation of pressure knob 16 to require a relatively high pressure at the "HIGH" position at 12 O'clock or a relatively low pressure at the "LOW" position at 6 O'clock markings. The knobs are operated by rotating the arrow on each knob to a desired rotational setting.

The regulator valve is closed and set on timed opening rather than pressure-sensor opening by turning regulator knob 15 to "TIMED" position at 6 O'clock on the dial. Time interval for opening the regulator valve by moving contractible member 1 away from base member 2 is determined by rotation of timer knob 17 to hours and portions of hours indicated clockwise on a dial around the outside periphery of timer knob 17.

Referring back to FIG 1, the motive member 4 is held mechanically by brake shoe 18 in whatever position it is moved by the plunger 5. Inward travel of the brake shoe 18 for braking effect is caused by biased pressure of brake spring 19 against brake plunger 20. Brake-releasing outward travel of the brake shoe 18 is caused by electrical charging of electrical brake coil 21. The electrically-motorized means to actuate release of brake shoe 18 can be a linear motor in which electrical current is directed to brake coil 21 from electrical current circuited to electrical coils 6. This causes the

7

brake plunger 21 to travel outwardly to release the brake regardless of which direction the valve plunger 5 is caused to travel. Thus, the valve plunger 5 is released to actuate travel of motive member 4 in either direction but held precisely in programmed positions without expenditure of electrical current when not actuated electrically.

5

There can be a series of brake shoes 18 and brake coils 21 circumferentially around the outside periphery of plunger 5. The brake shoes and the surface of the plunger can be made appropriate in size and physical nature to maximize effectiveness of this braking system. The surfaces of multiple brake shoes 18 and the surface of motive member 4 can be appropriately toothed or roughed and staggered for the brake shoes 18 to hold the motive member 4 precisely and reliably with only minimal tension and size of brake spring 19.

10

Low tension of brake spring 19 is desirable to minimize the current required to release the brake shoe 18 for travel of the motive member 4. This reduces the size of brake coil 21 as well as the size and amount of current required for electrical coil 6.

15

Referring to FIG 2, a pressure-sensing member 22 is biased against flexible tube 3 by pressure-transducer resilient member 23. Increase of pressure in flexible tube 3 actuates the outside periphery of the flexible tube 3 against the sensing member 22 and causes pressure-transducer resilient member 23 to contract and travel in a direction away from the flexible tube. This travel causes electrically-conductive transducer-plunger points 24 to contact matching stationary pressure transducer points 25. This contact can be programmed to signal opening travel of electromotive means 5.

20

25

Simultaneously with opening travel of electromotive means 5, electrical current can be circuited to activate audiovisual warning means 26 which is represented by a circular bell in FIG 2. This is designated by the words "AUDIOVISUAL WARNING" in a FIG 7 flow diagram.

30

The audiovisual warning means 26 can be a bell, a bell and light, or any combination of any type of sound-producing and sight-producing means. Either audio or visual warning means can be used separately without the other within the description and intent of this invention. It is foreseeable that the audiovisual means can be hard-wired to an outside transmitter such that a beeper, a phone, a speaker, lights, radio signals and other selections of warning devices would be actuated within the meaning of audiovisual warning as applied in this invention.

35

The brake coil 21 can be caused to release brake shoe 18 against brake resilient member 19 at the same time that the electromotive means 5 is caused to open the contractible member 1 and the audiovisual means 6 is actuated. This is illustrated variously in FIGs 1, 2, 3, 7, 8 and 9.

5 Referring to FIG 2, flow of fluid being regulated by this invention originates from a fluid source 27 and travels towards a fluid destination 28. When this invention is being employed as a bladder cyler, the fluid source 27 is the bladder of a patient and the fluid destination 28 is a means for disposing of urine from the bladder. When this invention is being utilized as
10 a programmable medication infusion system, the fluid source 27 is a medication reservoir and the fluid destination 28 is the blood stream or digestive tract of a patient. The main difference is in how it is used.

Functionally, the invention is substantially the same for bladder cycling as for inserting medication into the body of a patient. There are differences
15 only in the types of transducers and the programming utilized. For implantation in bodies of patients, however, the invention can be designed and constructed much smaller and large control knobs would be replaced with minute control members.

Differences in relation to transducers would include an optional chemical transducer 29 or an optional electrical transducer 30 in place of or in
20 addition to an optional pressure transducer with part numbers 22 through 25. An electrochemical transducer could be employed to combine the function of chemical transducer 29 and electrical transducer 30.

Details of particular chemical and electrical transducers are not
25 included in this invention. There is a wide variety that can be employed. Typically, chemical transducers would be activated by and measure pH ion concentration for acidity or alkalinity. pH is measured in two basic ways: (1) colorimetrically and (2) electrometrically. For on-line controls such as this invention, standard glass electrodes could be employed electrometrically.

30 Electrical transducers could be variations of the standard Wheatstone Bridge. This could measure accurately such factors as electrical resistance, capacitance and inductance in conjunction with electrochemical, electromechanical and electro-optical sensors in the body fluid of patients.

Other factors that could be measured and utilized for actuation of
35 transducers are flow rate, flow velocity, fluid viscosity, optical density, optical turbidity and optical color in relation to body fluid of patients.

For a variety of industrial and chemical applications of this invention,

variations of the principles employed for measurement and transducer actuation in relation to body fluid can be employed for regulating flow of other types of fluid.

5 A tubing flow-control section 31 can be attachable to flexible tubing at either or both the outlet and inlet sides of the contractible member 1 and base member 2. Such a tubing flow-control section 31 can be selectively collapsible and less resistant to movement of the motive member 4. This would decrease power requirements and thus decrease the size and weight of the invention. It would also decrease accumulation of fluid in the control
10 section 31 and thus also decrease conditions susceptible to buildup of contamination.

Resiliency of the flexible tube is important for many of the applications of this invention. Resiliency can be a tradeoff design factor with collapsibility for applications in which flow pressure is low enough for
15 collapsibility to deter flow. Thus, flexibility is intended to include sufficient resiliency of tubes through which flow is regulated with this invention.

At either or both sides of the control section 31, there can be sealable valves 32 for taking out or putting in fluid separately from flow of fluid
20 through the flexible tube 3. Depending on the application of the invention, these sealable valves 32 could be used to inject medication, a cultured substance or any modification or mix of the fluid at either the input or the outlet side of the valve. The sealable valves also could be used for sampling the fluid flowing through the control section 31. The sealable valves 32 also
25 could be positions at which additional control transducers could be added.

The entire flexible tube 3 can be collapsible for some applications. For some applications, the entire length of the tube 3 would be no longer than illustrated relatively for the control section 31. Both for bladder cycling and for medication infusion, collapsible tubing may be preferable for the
30 entire length of tubing employed.

When this invention is utilized for industrial or consumer applications not associated with health-care, medical and hospital uses, it can be constructed in sizes to match any size of tubing or pressure conditions. It can range in size for three-foot-diameter flexible tubing flow-control
35 sections 31 down to flow-control sections less than an eighth of an inch in diameter. It is significant also that fluid conveyances leading to and from this invention can be solid plumbing or other tubing and fluid conveyances

when the tubing flow-control section 31 is appropriately flexible, resilient or collapsible.

Referring to FIG 3, an embodiment of this invention employing chemical and electrical transducers is illustrated from the top with chemical transducer knob 33 and electrical transducer knob 34 in place of the pressure knob 16. This form of the invention is primarily for medication infusion. A timer knob 17 and a regulator knob 15 are shown at opposite ends of the invention for continuity and clarity of description. The invention is also shown proportionately smaller for inference of its smaller construction for implantability in the body of patients. It could be made smaller yet by placing all four knobs parallel and at right angles to each other. The knobs can be made much smaller and the mechanisms employed could be miniaturized for implantation. Abbreviations rather than words for chemical, electrical, open, close, high and low are used for decreasing size.

Miniaturization could be aided by appropriate collapsibility and yet resilience of tubing, particularly the tubing flow-control section 31 for the reasons described above.

The base member 2 in FIG 3 is shown narrower and shorter than in FIG 2 because it does not include the pressure transducer at that position. Also in FIG 3, the chemical transducer 29 and the electrical transducer 30 are shown for ease of illustration at opposite sides of a fluid destination 28. This is a partially schematic representation of separate transistors in relation to minute fluid disposition conditions in the body of a patient.

Illustrated schematically in FIGs 4, 5 and 6 are alternative components that are foreseeable as mechanisms included within the basic description of this invention. Portions of these schematics not illustrated or described are assumed to be well-known to those skilled in the art to which they apply.

Included in FIG 4 are geared rotational motor 35, preferably a reversible step motor, which rotates a shaft 36 to which a gear wheel 37 is attached. The gear wheel 37 can be "worm" geared for actuation of geared motive member 38 linearly to the axis of the shaft 36. Attached to the geared motive member 38 is an inclined cam 39 which actuates dual cam-follower 40 at right angles to the axis of rotational motor 35 and actuates a rotational-motor motive member 41 with rotational-motor contractible member 42 attached. The contractible member 42 is caused to travel in directions towards and away from rotational-motor base member 43 by opposite-directional rotation of rotational motor 35.

11

Opposite sides of flexible tube 3 are caused thereby to be pressed together or allowed to open selectively by fluid pressure within the tube and or by resiliency of the tube for achieving regulation of flow through the flexible tube.

5 Features of the invention not illustrated in relation to the schematic representations are assumed to be similar to those described in relation to other illustrations and related descriptions.

10 Illustrated in FIG 5, geared linear motor 44, preferably a step motor, actuates linearly in both directions a linear-motor shaft 45 to which a direct-drive motive member 46 is attached. On the direct-drive motive member 46 is linear-motor inclined cam 47 which actuates linear-motor dual cam follower 48. Attached to linear-motor dual cam follower 48 is linear-motor contractible member 49 which is actuated in both directions selectively towards and away from linear-motor base member 50 by opposite-directional
15 linear travel of linear-motor shaft 45.

20 Illustrated in FIG 6, a levered linear motor 51 is swivelably attached to inside lever arm 52. Levered linear-motor shaft 53 with attachment member 54 is swivelably attached to outside lever arm 55. Lever arms 52 and 55 are swivelably attached to fulcrum 56. Selectively opposite-directional linear travel of levered linear-motor shaft 53 causes levered linear-motor contractible member 57 to travel selectively towards and away from levered linear-motor base member 58.

25 Referring to FIG 7, a flow diagram of a bladder-cycler embodiment of this invention is illustrated with the components indicated by words. Fluid flows from a "BLADDER" to a "VALVE" and then to a "DISPOSITION COUPLING." At the valve, alternative programs of either a timer, a pressure transducer or an override are selected for fluid flow to reach a disposition point at the disposition coupling. Programmed pressure operation of the valve is selected by rotating the regulator knob 15 in FIG 2 to "SENSOR." Programming can be
30 set for a relatively high or low pressure by rotating the "PRESSURE" knob 16 to "HIGH" and "LOW" settings respectively as illustrated further in FIG 2. The "BRAKE" will maintain the valve in a closed position with contractible member 1 pressing the sides of flexible tube 3 against the base member 2 until the designated pressure is reached. When the pressure-sensing member 22 is
35 activated as programmed, there will be an audiovisual warning as designed and programmed, the brake shoe 18 will release the motive member 4 and fluid will be allowed to flow through the flexible tube.

12

If, in addition, the regulator knob 15, illustrated in FIG 2, is rotated to one side or the other of 12 O'clock position, the proportion of full open condition of the valve will be determined by the relative rotation of regulator knob 15 towards open and shut respectively. When a programmed low pressure has been reached, the valve will again close and remain in a closed position by action of brake shoe 18 until a programmed higher pressure is reached in the tubing flow-control section 31.

Timed opening is programmed by rotating the regulator knob 18 in FIG 2 to "TIMER" at 6 O'clock. Then the time period between openings is selected by rotating the timer knob 17 to the indicated hours and portions of hours clockwise on the timer dial. At the time intervals programmed accordingly, the valve will open by travel of contractible member 1 away from the base member 2 and the flexible tube 3. When the valve opens, the audiovisual warning will be activated and the brake will be released and reset with the valve in open condition. When flow has stopped as indicated by absence of pressure in the tube against the pressure-sensing member 22, the brake will be released from open condition, the valve will be shut and the brake will be set again to maintain closed condition without expenditure of electrical energy for continued braking action.

Referring to FIG 8, a flow diagram of the medication-insertion embodiment in FIG 3 is illustrated with components indicated by descriptive words. Fluid flows from a "MEDICATION RESERVOIR" to a "VALVE" and then to an "INSERTION COUPLING." At the valve in the medication-infusion application, alternative programs of either a timer, chemical transducer, electrical transducer or manual override are selected for fluid flow to reach a destination at the insertion coupling. To select programming for either or both of the chemical and electrical transducers, the regulator knob 15 is rotated to where the arrow points to "VALVE."

The knobs are marked with "CH" for the chemical knob and "EL" for the electrical knob. Either or both knobs are programmed by first rotation to a position clockwise or counterclockwise from "H" for high. If the knobs are rotated to any position of rotation between "H" and "L" at the half-circle side marked "C" for closed, the valve will remain open until a relatively high or low chemical or electrical condition being programmed for is reached according to the relative rotation of the arrow between "H" and "L." When the selective condition is reached, the valve will close.

If the knobs are rotated to any position of rotation between "H" and "L"

at the half-circle side of the dial marked "O" for open, the valve will remain closed until a setting for opening is reached according to the position of rotation of the arrow in relation to "H" and "L."

Both knobs must be on the "O" or the "C" side of the dial circles if both
5 electrical and chemical transducers are being programmed. Otherwise, one will cancel the other out because there is only one valve for both. This is consonant with programming regimes for medication infusion because generally the valve should stay either open or closed until either or both chemical and electrical conditions occur.

10 Timed opening or closing of the valve is selected the same for the FIG 3 embodiment as for the FIG 2 embodiment.

The FIG 8 flow diagram indicates "VARIABLE OPEN-SHUT," "AUDIOVISUAL WARNING" and "BRAKE" for the transducers and for the timer selections. Variable open and shut are selected as described above by rotation of the
15 arrow on each knob to the relative position of chemical and electrical conditions or of open or closed conditions that are programmed with rotation of the knobs. Actuation of the brake and the audiovisual warning can be automatically simultaneous as programmed the same as described above for FIG 2 in relation bladder cycling.

20 Other uses of this invention for industrial and consumer uses can employ similar programming and control parameters, depending on the particular applications.

Referring to FIG 9, an electrical circuit diagram is illustrated with descriptive words and symbols. From an "ELECTRICAL SOURCE," current flows
25 to a "BATTERY CHARGE CONTROL" and then to a "CONVERTER."

The battery charge-control unit is separate from the battery to prevent potential electrical hazards. Shock-level electrical current is prevented from reaching a patient when a low-voltage batter is being employed as described above. A converted is employed to convert various levels of current
30 to the particular applications for transducer use and for valve-motor operation. This division of current is indicated functionally in the diagram by "POWER TO LOADS."

Current flows to a "PRESSURE TRANSDUCER," as indicated by the arrow, and then to switching mechanisms for the "VALVE MOTOR." Current flows separately
35 to the valve motor because a relatively greater amount of current is required to operate the valve motor than the transducer mechanisms and switches. Transducer switches are indicated by the circled arrows. At the same time

14

current flows to the valve motor, current flows also to the brake and warning devices as outlined in the flow diagrams, FIGs 7 and 8. Electrical power to operate the brake and warning devices can be in line with flow of current to the valve motor. Electrical current to operate transducers which actuate the brake and warning mechanisms can be in line with the current to the pressure transducer.

Current flows to a "VALVE TIMER," to "OTHER TRANSDUCERS" and to an "OVERRIDE" in the same manner as to the pressure transducer. Other transducers can be any type or combination of types of transducers for any application of this device. Current flows separately to the "VALVE MOTOR." Activation switches can be operated in line with the timer, transducers and override while mechanisms associated with the valve motor can be operated by current in line with the valve motor.

Current returns to the converter and the battery at the point where power is transmitted to loads associated with the mechanisms employed.

A wide variation of many additional combinations of the components comprising this device are foreseeable. All such are deemed to be within the scope of this invention although only a select relatively few are described to teach the general nature of this invention in the following claims.

15

CLAIMS

What is claimed is:

1. A programmable flexible-tube flow regulator comprising:
 - a contractible apparatus for pressing opposite sides of a flexible tube together such that flow of fluid through the flexible tube is allowed and prevented selectively in accordance with how closely the opposite sides of the tube are pressed together;
 - an electrically-motorized means for actuating the contractible apparatus to a closed position to restrict flow and to a selectively open position to allow flow of fluid through the flexible tube selectively;
 - a programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively and;
 - a select voltage of electrical power in electrical current relationship from an electrical source to the electrically-motorized means and to the programmable control means;
2. A programmable flexible-tube flow regulator according to claim 1 and further comprising:
 - a pressure sensor actuated by pressure within the flexible tube to signal the electrically-motorized means to actuate the contractible apparatus to an open position at the occurrence of selective fluid pressure within the flexible tube.
3. A programmable flexible-tube flow regulator according to claim 2 and further comprising:
 - a manual override of the programmable control means and the pressure sensor to allow manual actuation of the contractible apparatus to closed and open positions selectively.
4. A programmable flexible-tube flow regulator according to claim 1 and further comprising:
 - a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member selectively by the electrically-motorized means and;
 - a linear electrical brake motor conductor plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical source such that flow of current through the electrically-motorized means also causes flow of current through the brake

16

coil to release the brake shoe whenever the electrically-motorized means for the contractible apparatus is actuated.

5. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

5 an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

6. A programmable flexible-tube flow regulator according to claim 1
10 wherein the programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively is programmable for time intervals of closed and selectively open positions of the contractible apparatus.

7. A programmable flexible-tube flow regulator according to claim 1
15 wherein the flexible tube is a medical catheter insertable into a bladder.

8. A programmable flexible-tube flow regulator according to claim 7 and further comprising:

20 a fluid discharge tube extendible from the flow regulator to a fluid-disposition means.

9. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

a medication reservoir;

25 a medication-infusion tube extendible from the reservoir to the flow regulator;

a medication infuser insertable selectively into the blood-stream system and;

a medication-infusion tube extendible from the flow regulator to the fluid infuser.

30 10. A programmable flexible-tube flow regulator according to claim 9 and further comprising:

a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member
35 selectively by the electrically-motorized means and;

a linear electrical brake motor conductor plunger attached to the brake shoe and extended through an electrical brake coil with electrical current

directed from the electrical source such that flow of current through the electrically-motorized means also causes flow of current through the brake coil to release the brake shoe whenever the electrically-motorized means for the contractible apparatus is actuated.

5 11. A programmable flexible-tube flow regulator according to claim 10 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with
10 conditions programmed into the programmable control means.

12. A programmable flexible-tube flow regulator according to claim 11 and further comprising:

a manual override of the programmable control means and the pressure sensor to allow manual actuation of the contractible apparatus to closed and
15 open positions selectively.

13. A programmable flexible-tube flow regulator according to claim 12 wherein the programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively is programmable for time intervals of closed and selectively open
20 positions of the contractible apparatus.

14. A programmable flexible-tube flow regulator according to claim 13 and further comprising:

an electrical transducer in electrical-conductivity-sensing relationship
25 between the programmable control means and the blood of a patient.

15. A programmable flexible-tube flow regulator according to claim 14 and further comprising:

a chemical transducer in selective chemical-analysis relationship between the programmable control means and the blood of a patient.

30 16. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

a medication reservoir;

a medication-infuser tube extendible from the reservoir to the flow regulator;

35 a medication infuser insertable selectively into the digestive-tract system of a patient and;

a medication-infuser tube extendible from the flow regulator to the

medication infuser.

17. A programmable flexible-tube flow regulator according to claim 16 and further comprising:

5 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member selectively by the electrically-motorized means and;

10 a linear electrical brake motor conductor plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical source such that flow of current through the electrically-motorized means also causes flow of current through the brake coil to release the brake shoe whenever the electrically-motorized means for the contractible apparatus is actuated.

15 18. A programmable flexible-tube flow regulator according to claim 17 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

20 19. A programmable flexible-tube flow regulator according to claim 18 wherein the programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively is programmable for time intervals of closed and selectively open positions of the contractible apparatus.

25 20. A programmable flexible-tube flow regulator according to claim 19 and further comprising:

an electrical transducer in electrical-conductivity-sensing relationship between the programmable control means and the digestive tract of a patient.

30 21. A programmable flexible-tube flow regulator according to claim 20 and further comprising:

a chemical transducer in selective chemical-analysis relationship between the programmable control means and the digestive tract of a patient.

35 22. A programmable flexible-tube flow regulator according to claim 21 and further comprising:

a manual override of the programmable control means and the electrical and chemical transducers to allow manual actuation of the contractible

apparatus to closed and open positions selectively.

23. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

an enclosure through which a flexible tube is insertable;

5 a base member at one side of the inside periphery of the enclosure;

an electrically-motorized means comprising a controllable-step linear electrical motor with linear travel at right angles to the travel of the contractible member;

10 inclined surfaces extended from a plunger of the electrical motor in slidable inclined-plane relationship to the contractible member such that linear travel of the electrical-motor plunger at right angles to the direction of travel of the contractible member causes the inclined plane to actuate the contractible member in the direction of the base member and slidable travel of the plunger in the opposite direction from the contractible member causes the
15 inclined plane to actuate the contractible member in a direction away from the base member.

24. A programmable flexible-tube flow regulator according to claim 23 and further comprising:

20 a programmable control means in electrical-circuit-control relationship to the controllable-step linear motor and;

a control-input board having input control knobs in mechanical-electrical operative relationship to the programmable control means.

25. A programmable flexible-tube flow regulator according to claim 24 wherein the programmable control means is programmable for time intervals, pressure-sensing signals and is provided with manual override for actuating the electrically-motorized means in the direction of the base member and in the opposite direction from the base member selectively.

26. A programmable flexible-tube flow regulator according to claim 25 and further comprising:

30 a pressure sensor at the inside periphery of the said enclosure in radially-outward pressure-sensing relationship to a flexible tube insertable through the enclosure between the base member and the contractible member and;

a pressure-meter signalling means in pressure-signalling relationship between the pressure sensor and the programmable control means.

35 27. A programmable flexible-tube flow regulator according to claim 26 and further comprising:

a brake shoe actuated by a spring against the contractible apparatus to

arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member selectively by the electrically-motorized means and;

5 a linear electrical brake motor conductor plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical source such that flow of current through the electrically-motorized means also causes flow of current through the brake coil to release the brake shoe whenever the electrically-motorized means for the contractible apparatus is actuated.

10 28. A programmable flexible-tube flow regulator according to claim 27 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

15 29. A programmable flexible-tube flow regulator according to claim 28 and further comprising:

a selectively collapsible tube extendible through the enclosure and attachable selectively to discharge and infusion tubes at an outlet end of the enclosure and to catheter and medication supply tubes at an inlet end of the enclosure.

20 30. A programmable flexible-tube flow regulator according to claim 29 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of the inlet end of the enclosure.

25 31. A programmable flexible-tube flow regulator according to claim 30 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of the outlet end of the enclosure.

30 32. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

a clamping means with one open side into which a flexible tube is insertable from side-to-side;

a base member at one side of the clamping means;

35 a contractible member with slidable travel selectively towards and away from the base member in sliding means on the clamping means;

an electrically-motorized means comprising a controllable-step rotational

motor with linearly-gear ed electromotive relationship to a motive member such that selective inputs of electrical current into the controllable-step rotational motor cause the motive member to travel in the direction of or in the opposite direction from the contractible member in accordance with selective inputs of electrical current and;

Inclined surfaces on the motive member in slidable inclined-plane relationship to the contractible member such that linear travel of the motive member in the direction of the contractible member causes the inclined plane to actuate the contractible member in the direction of the base member and linear travel of the motive member in the opposite direction from the contractible member causes the inclined plane to actuate the contractible member in a direction away from the base member.

33. A programmable flexible-tube flow regulator according to claim 32 and further comprising:

a programmable control means in electrical-circuit-control relationship to the controllable-step rotational motor and;

a control-input board having input control knobs in mechanical-electrical operative relationship to the programmable control means.

34. A programmable flexible-tube flow regulator according to claim 33 wherein the programmable control means is programmable for time intervals, pressure-sensing signals and is provided with manual override for actuating the electrically-motorized member.

35. A programmable flexible-tube flow regulator according to claim 34 and further comprising:

a pressure sensor at the inside periphery of the said clamping means in radially-outward pressure-sensing relationship to a flexible tube insertable into the clamping means between the base member and the contractible member and;

a pressure-meter signalling means in pressure-signalling relationship between the pressure sensor and the programmable control means.

36. A programmable flexible-tube flow regulator according to claim 35 and further comprising:

a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member selectively by the electrically-motorized means and;

a linear electrical brake motor conductor plunger attached to the brake

shoe and extended through an electrical brake coil with electrical current directed from the electrical source such that flow of current through the electrically-motorized means also causes flow of current through the brake coil to release the brake shoe whenever the electrically-motorized means for the contractible apparatus is actuated.

37. A programmable flexible-tube flow regulator according to claim 36 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

38. A programmable flexible-tube flow regulator according to claim 37 and further comprising:

a selectively collapsible tube insertable from side-to-side into the clamping means and attachable selectively to discharge and infusion tubes at an outlet end of the clamping means and to catheter and medication supply tubes at an inlet end of the clamping means.

39. A programmable flexible-tube flow regulator according to claim 38 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of the inlet end of the clamping means.

40. A programmable flexible-tube flow regulator according to claim 39 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of the outlet end of the clamping means.

41. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

a clamping means with one open side into which a flexible tube is insertable from side-to-side;

a base member at one side of the clamping means;

a contractible member with slidable travel selectively towards and away from the base member in sliding means on the clamping means;

a motive member with slidable travel at right angles to the travel of the contractible member in sliding means within the clamping means;

inclined surfaces on the motive member in slidable inclined-plane relationship to the contractible member such that slidable travel of the motive member in the direction of the contractible member causes the inclined

plane to actuate the contractible member in the direction of the base member and slidable travel of the motive member in the opposite direction from the contractible member causes the inclined plane to actuate the contractible member in a direction away from the base member and;

5 an electrically-motorized means comprising a controllable-step linear electrical motor with linear travel of a conductor plunger in relationship to the motive member such that selective inputs of electrical current into the controllable-step motor cause the motive member to travel in the direction of or in the opposite direction from the contractible member in accordance with
10 the selective inputs of electrical current.

42. A programmable flexible-tube flow regulator according to claim 41 and further comprising:

 a programmable control means in electrical-circuit-control relationship to the controllable-step linear motor and;

15 a control-input board having input control knobs in mechanical-electrical operative relationship to the programmable control means.

43. A programmable flexible-tube flow regulator according to claim 42 wherein the programmable control means is programmable for time intervals, pressure-sensing signals and is provided with manual override for actuating
20 the electromotive member in the direction of the base member and in the opposite direction from the base member selectively.

44. A programmable flexible-tube flow regulator according to claim 43 and further comprising:

 a pressure sensor at the inside periphery of the said clamping means in
25 radially-outward pressure-sensing relationship to a flexible tube insertable into the clamping means between the base member and the contractible member and;

 a pressure-meter signalling means in pressure-signalling relationship between the pressure sensor and the programmable control means.

30 45. A programmable flexible-tube flow regulator according to claim 44 and further comprising:

 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member
35 by the electrical motor and;

 a linear electrical motor conductor brake plunger attached to the brake shoe and extended through an electrical brake coil with electrical current

24

directed from the electrical motor such that flow of current through the electrical motor also causes flow of current through the brake coil to release the brake against the pressure from the brake spring whenever the electrical motor operating the contractible apparatus is actuated.

5 46. A programmable flexible-tube flow regulator according to claim 45 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with
10 conditions programmed into the programmable control means.

47. A programmable flexible-tube flow regulator according to claim 46 and further comprising:

a selectively collapsible tube insertable from side-to-side into the clamping means and attachable selectively to discharge and infusion tubes at
15 an outlet end of the clamping means and to catheter and medication supply tubes at an inlet end of the clamping means.

48. A programmable flexible-tube flow regulator according to claim 47 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of
20 the inlet end of the clamping means.

49. A programmable flexible-tube flow regulator according to claim 48 and further comprising:

a sealable fluid-input orifice in a side of the tube at the vicinity of
the outlet end of the clamping means.

25 50. A programmable flexible-tube flow regulator according to claim 1 in which the contractible apparatus is a plier-like clamping means with a fulcrum in relationship to which two arms are pivotally attached and further comprising:

a motive member with expandable and contractible travel selectively in
30 relationship to the two arms at the opposite side of the fulcrum from positions on the two arms between which the flexible tube is insertable and;

an electrically-motorized means comprising a controllable-step linear electrical motor with linear-travel relationship of a conductor plunger to the motive member such that selective inputs of electrical current into the
35 controllable-step linear motor actuate the motive member to spread the two arms to close the plier-like clamping means and to draw the two arms together to open the plier-like clamping means selectively at the opposite side of the

25

fulcrum from the linear motor.

51. A programmable flexible-tube flow regulator according to claim 50 and further comprising:

5 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions which open or close the plier-like clamping means selectively and;

10 a linear electrical motor conductor brake plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical motor such that flow of current through the electrical motor also causes flow of current through the brake coil to release the brake against the pressure from the brake spring whenever the electrical motor operating the plier-like contractible apparatus is actuated.

52. A programmable flexible-tube flow regulator according to claim 15 51 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

20 53. A programmable flexible-tube flow regulator according to claim 52 and further comprising:

25 a pressure sensor actuated by pressure within the flexible tube to signal the electrically-motorized means to actuate the contractible apparatus to an open position at the occurrence of selective fluid pressure within the flexible tube;

a manual override of the programmable control means and the pressure sensor to allow manual actuation of the contractible apparatus to closed and open positions selectively;

30 54. A programmable flexible-tube flow regulator according to claim 1 wherein the contractible apparatus is a plier-like clamping means with a fulcrum in relationship to which two arms are pivotally attached and further comprising:

35 a motive member with expandable and contractible travel selectively in relationship to the two arms at the opposite side of the fulcrum from positions on the two arms between which the flexible tube is insertable;

a controllable-step linear electrical motor with linear-travel relationship of a conductor plunger to the motive member such that selective

26

inputs of electrical current into the controllable-step linear motor actuate the motive member to spread the two arms to close the plier-like clamping means and to draw the two arms together to open the plier-like clamping means selectively at the opposite side of the fulcrum from the linear motor;

5 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to open and close the plier-like contractible member selectively;

10 a linear electrical motor conductor brake plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical motor such that flow of current through the electrical motor also causes flow of current through the brake coil to release the brake against the pressure from the brake spring whenever the electrical motor operating the contractible apparatus is actuated;

15 a medication reservoir;

a medication-infuser tube extendible from the reservoir to the flow regulator;

a medication infuser insertable selectively into the digestive-tract system of a patient and;

20 a medication-infuser tube extendible from the flow regulator to the medication infuser.

55. A programmable flexible-tube flow regulator according to claim 54 and further comprising:

25 an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

56. A programmable flexible-tube flow regulator according to claim 55 and further comprising:

30 a chemical transducer in selective chemical-analysis relationship between the programmable control means and selected body fluids of a patient.

57. A programmable flexible-tube flow regulator according to claim 56 and further comprising:

35 an electrical transducer in electrical-conductivity-sensing relationship between the programmable control means and selected body fluids of a patient.

58. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

a clamping means into which a flexible tube is insertable from side-to-side;

a base member at one side of the clamping means;

5 a contractible member with slidable travel selectively towards and away from the base member in sliding means on the clamping means;

a motive member with slidable travel linearly to the travel of the contractible member;

10 an electrically-motorized means comprising a controllable-step linear electrical motor having a conductor plunger in linear travel relationship to the motive member such that selective inputs of electrical current into the controllable-step linear electrical motor cause the motive member to travel in the direction of or in the opposite direction from the contractible member in accordance with the selective inputs of electrical current;

15 a pressure sensor actuated by pressure within the flexible tube to signal the electrically-motorized means to actuate the contractible apparatus to an open position at the occurrence of selective fluid pressure within the flexible tube;

20 a manual override of the programmable control means and the pressure sensor to allow manual actuation of the contractible apparatus to closed and open positions selectively and;

a control-input board having input control knobs in mechanical-electrical operative relationship to the programmable control means.

25 59. A programmable flexible-tube flow regulator according to claim 58 wherein the programmable control means is programmable for time intervals and pressure-sensing signals and is provided with manual override for actuating the motive member in the direction of the base member and in the opposite direction from the base member selectively.

30 60. A programmable flexible-tube flow regulator according to claim 59 and further comprising a pressure signalling means in pressure-signalling relationship between the pressure sensor and the programmable control means.

61. A programmable flexible-tube flow regulator according to claim 60 and further comprising:

35 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in directions towards and away from the base member by the electrical motor and;

a linear electrical motor conductor brake plunger attached to the brake

shoe and extended through an electrical brake coil with electrical current directed from the electrical motor such that flow of current through the electrical motor also causes flow of current through the brake coil to release the brake against the pressure from the brake spring whenever the electrical motor operating the contractible apparatus is actuated.

5 62. A programmable flexible-tube flow regulator according to claim 61 and further comprising:

an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that
10 selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

63. A programmable flexible-tube flow regulator according to claim 62 and further comprising;

a selectively collapsible tube insertable into the contraction means and
15 attachable selectively to discharge and infusion tubes at an outlet end of the contraction means and to catheter and medication supply tubes at an inlet end of the contraction means.

64. A programmable flexible-tube flow regulator according to claim 63 and further comprising:

20 a sealable fluid-input orifice in a side of the flexible tube selectively at the vicinity of an inlet side and an outlet side of the contraction means.

65. A programmable flexible-tube flow regulator according to claim 64 and further comprising:

a tube holding and protection member foldable over a portion of the
25 contraction means into which the flexible tube is insertable.

66. A programmable flexible-tube flow regulator according to claim 65 wherein the programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube
30 selectively is programmable for time intervals of selective open and closed positions of the contractible apparatus.

67. A programmable flexible-tube flow regulator according to claim 66 wherein the flexible tube is a medical catheter insertable into a bladder.

68. A programmable flexible-tube flow regulator according to claim
35 67 and further comprising:

an electrical-hazard-protection means with a charger separate from the electrical supply means within the regulator and having a selectively low

29

current in communication between an electrical source and the said electrical supply means within the regulator such that the regulator can be charged when in use without danger of over-supply of electrical current to the said regulator when it is in use.

5 69. A programmable flexible-tube flow regulator according to claim 1 and further comprising:

 a clamping means into which a flexible tube is insertable from side-to-side;

 a base member at one side of the clamping means;

10 a contractible member with slidable travel selectively towards and away from the base member in sliding means on the clamping means;

 a motive member with slidable travel linearly to the travel of the contractible member;

15 an electrically-motorized means comprising a controllable-step linear electrical motor having a conductor plunger in linear travel relationship to the motive member such that selective inputs of electrical current into the controllable-step linear electrical motor cause the motive member to travel in the direction of or in the opposite direction from the contractible member in accordance with the selective inputs of electrical current;

20 a manual override of the programmable control means to allow manual actuation of the contractible apparatus to closed and open positions selectively;

 a control-input board having input control knobs in mechanical-electrical operative relationship to the programmable control means;

25 a medication reservoir;

 a medication-infuser tube extendible from the reservoir to the flow regulator;

 a medication infuser insertable selectively into the digestive-tract system of a patient and;

30 a medication-infuser tube extendible from the flow regulator to the medication infuser.

 70. A programmable flexible-tube flow regulator according to claim 69 and further comprising:

35 a chemical transducer in selective chemical-analysis relationship between the programmable control means and selected body fluids of a patient.

 71. A programmable flexible-tube flow regulator according to claim 70 and further comprising:

30

an electrical transducer in electrical-conductivity-sensing relationship between the programmable control means and selected body fluids of a patient.

72. A programmable flexible-tube flow regulator according to claim 71 and further comprising:

5 a brake shoe actuated by a spring against the contractible apparatus to arrest travel of the contractible apparatus when the contractible apparatus is not being caused to travel in a direction towards or away from the base member by the electrical motor and;

10 a linear electrical motor conductor brake plunger attached to the brake shoe and extended through an electrical brake coil with electrical current directed from the electrical motor such that flow of current through the electrical motor also causes flow of current through the brake coil to release the brake against the pressure from the brake spring whenever the electrical motor operating the contractible apparatus is actuated.

15 73. A programmable flexible-tube flow regulator according to claim 72 and further comprising:

20 an audiovisual warning signal in electrical communication between the contractible apparatus and the programmable control means such that selectively audio and visual warning is initiated in accordance with conditions programmed into the programmable control means.

25 74. A programmable flexible-tube flow regulator according to claim 73 wherein the programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively is programmable for time intervals of selectively open and closed positions of the contractible apparatus.

75. A programmable flexible-tube flow regulator according to claim 74 and further comprising:

30 an electrical-hazard-prevention means having a charger separately from the electrical supply means in the regulator and a selectively low current in communication between an electrical source and the said electrical supply means within the regulator such that the regulator can be charged when in use without danger of over-supply of electrical current to the said regulator when it is in use.

35 76. A method for using a programmable flexible-tube flow regulator consisting of:

a contractible apparatus for pressing opposite sides of a flexible tube

31

together selectively;

a electrically-motorized means for actuating the contractible apparatus to a closed position to restrict flow and to a selectively open position to allow flow of fluid through the flexible tube selectively;

5 a programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively;

a selectively low voltage electrical power source in electrical current relationship to the electrically-motorized means and the programmable control means;

10 a pressure sensor actuated by pressure within the flexible tube to signal the electrically-motorized means to actuate the contractible apparatus to an open position at the occurrence of selective fluid pressure within the flexible tube;

15 a manual override of the programmable control means and the pressure sensor to allow manual actuation of the contractible apparatus to closed and open positions selectively;

a catheter tube insertable into a bladder and extendible between the bladder and the flow regulator and;

20 a discharge conveyance between the flow regulator and a discharge means and

comprising:

Inserting the catheter tube into the bladder of a patient;

25 securing the flow regulator at a position convenient to the patient outside of the bladder;

Inserting a section of tube that is connected to the catheter tube outside of the patient into the contractible apparatus of the flow regulator;

securing a fluid discharge means at a level below the patient;

30 positioning a fluid conveyance means in fluid communication between the discharge means and the flow regulator;

adjusting the pressure sensor to open the flow regulator at the occurrence of predetermined pressure within the catheter tube and predetermined time intervals selectively and;

35 overriding the pressure and time controls manually as necessary for adjustment of the programmable controls to the needs of particular patients in the process of cycling the emptying and shutting off of discharge from the bladder of a patient.

32

77. A method of using a programmable flexible-tube flow regulator consisting of:

a contractible apparatus for pressing opposite sides of a flexible tube together selectively;

5 a electrically-motorized means for actuating the contractible apparatus to a closed position to restrict flow and to a selectively open position to allow flow of fluid through the flexible tube selectively;

10 a programmable control means for causing the electrically-motorized means to actuate the contractible apparatus to closed and open positions to prevent and to allow flow of fluid through the flexible tube selectively;

a selectively low voltage electrical power source in electrical current relationship to the electrically-motorized means and the programmable control means;

15 a medication reservoir;

a medication conveyance in fluid communication between the medication reservoir and the contractible apparatus of the flow regulator;

a medication infuser;

20 a medication conveyance in fluid communication between the flow regulator and the medication infuser;

an electrochemical transducer programmable to open and close the contractible apparatus selectively in accordance with electrochemical conditions in the body of a patient;

25 an infusion timer programmable for time intervals of open and selectively closed positions of the contractible apparatus;

a manual override of the programmable control means, the timer and the electrochemical transducer to allow manual actuation of the contractible apparatus to closed and open positions selectively and;

30 an audiovisual warning means in predeterminable electrically-operative communication between the programmable control means and select electrochemical conditions in the body of a patient and

comprising:

Inserting the medication infuser into a select fluid stream of the body of a patient;

35 securing the medication reservoir and the flow regulator to a convenient position in relation to the body of the patient;

Inserting a section of the medication conveyance tube into the contractible apparatus of the flow regulator;

33

adjusting the electrochemical transducer to open the flow regulator selectively at the occurrence of predetermined electrochemical conditions in the body of the patient and;

5 overriding the electrochemical and time controls manually as necessary for adjustment of a program for controlled flow of medication with the programmable control means to the needs of particular patients.

10

15

20

25

30

35

1/4

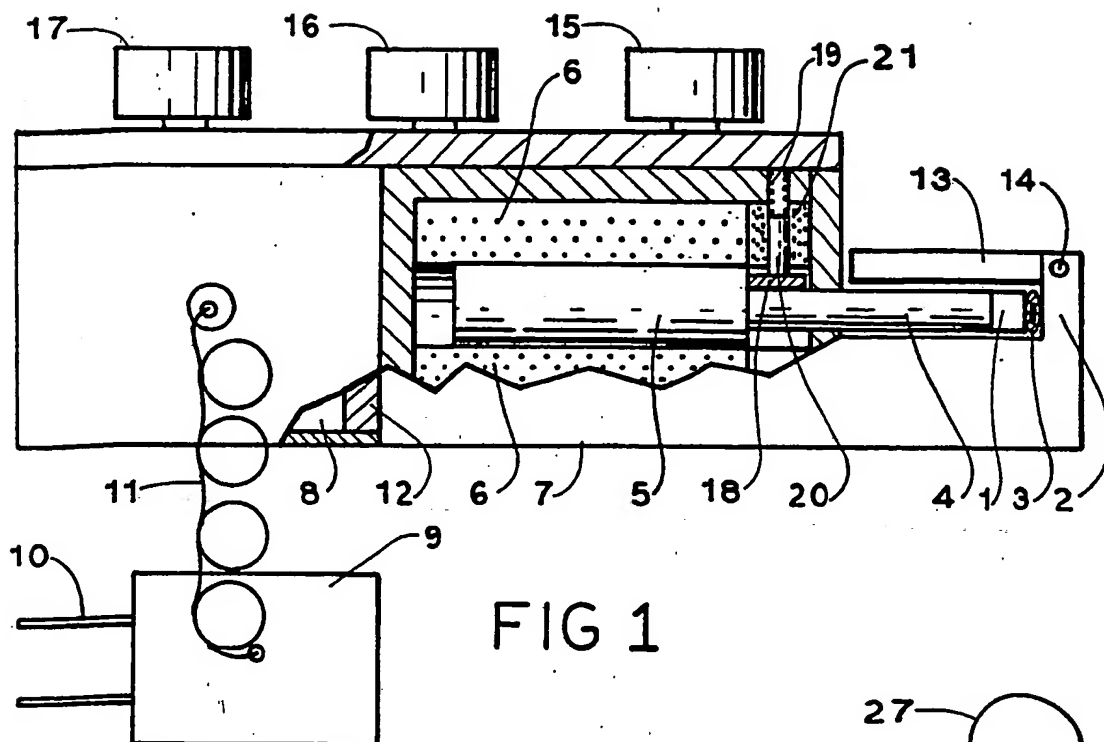


FIG 1

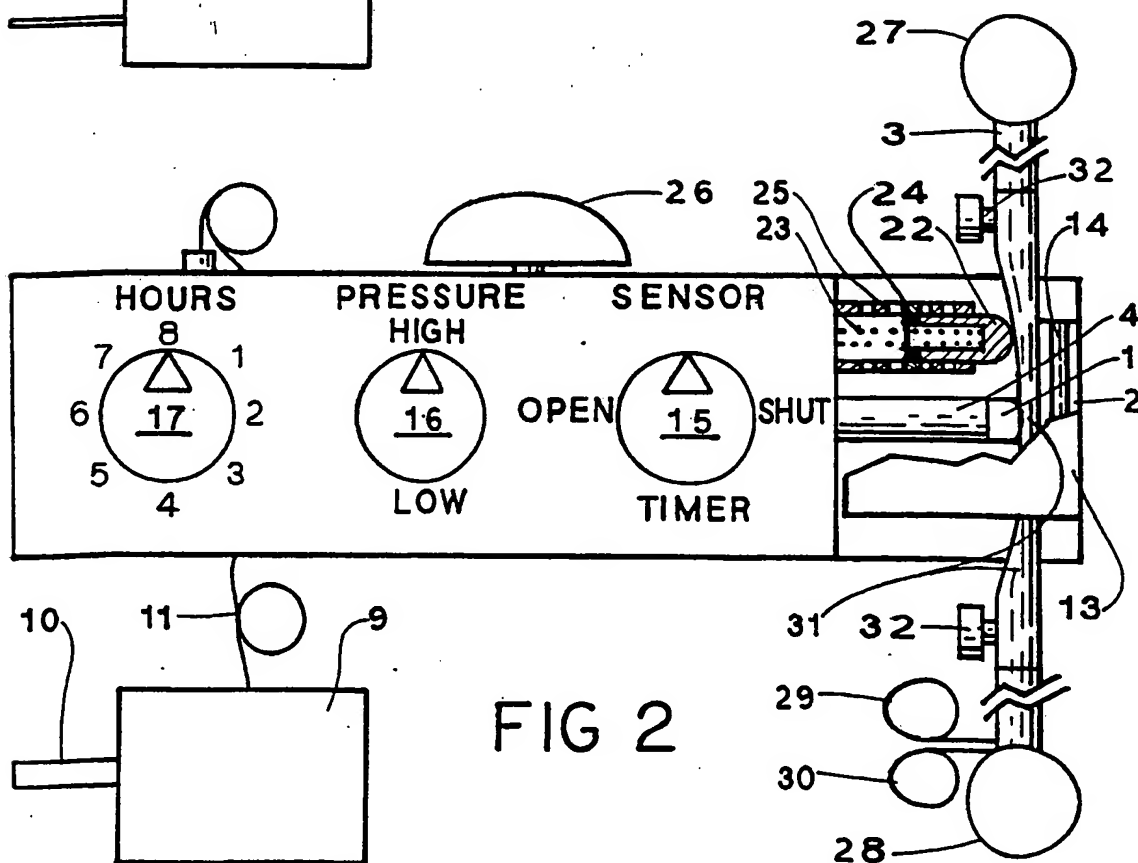


FIG 2

2/4

FIG 3

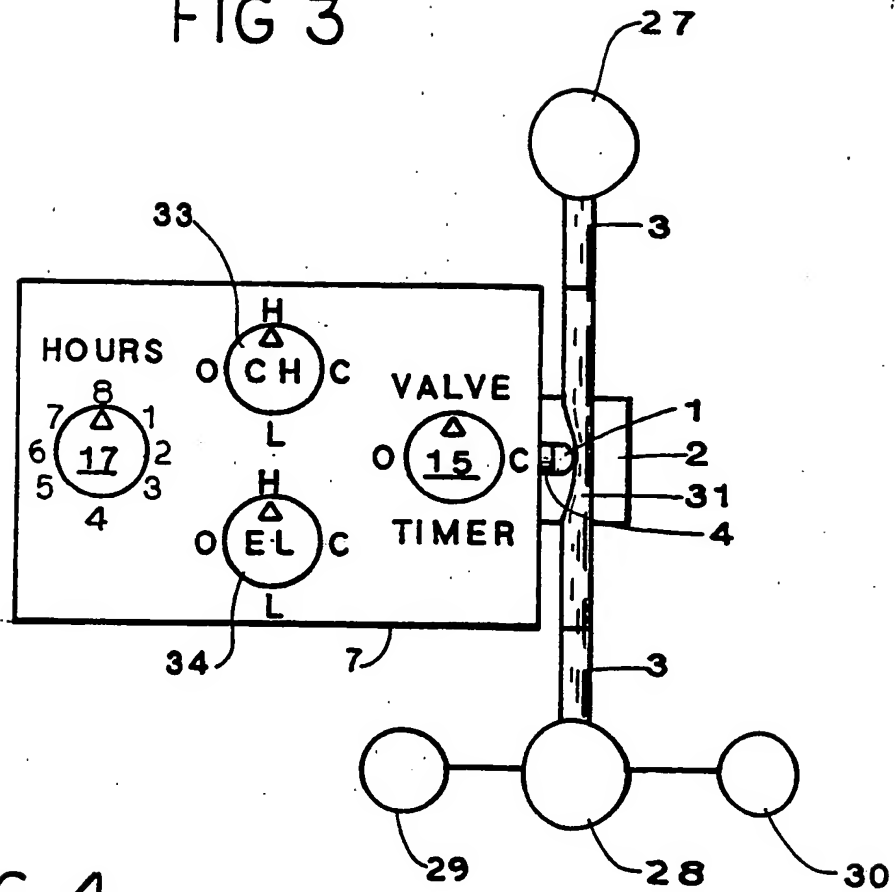


FIG 4

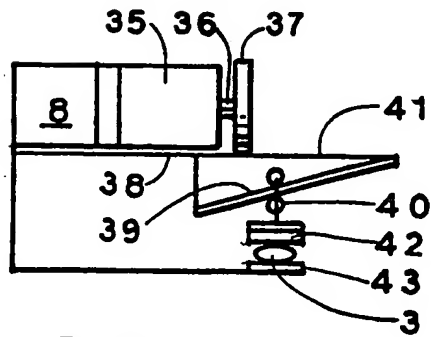


FIG 5

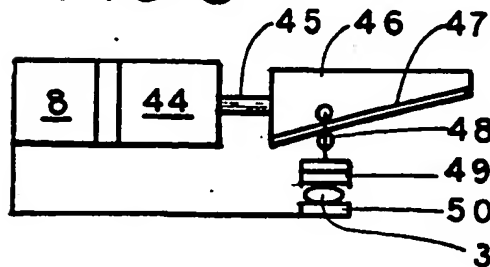
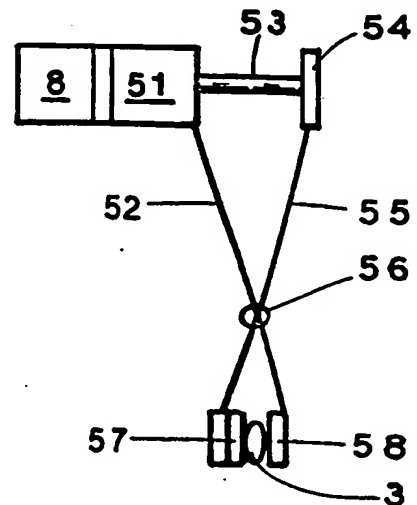
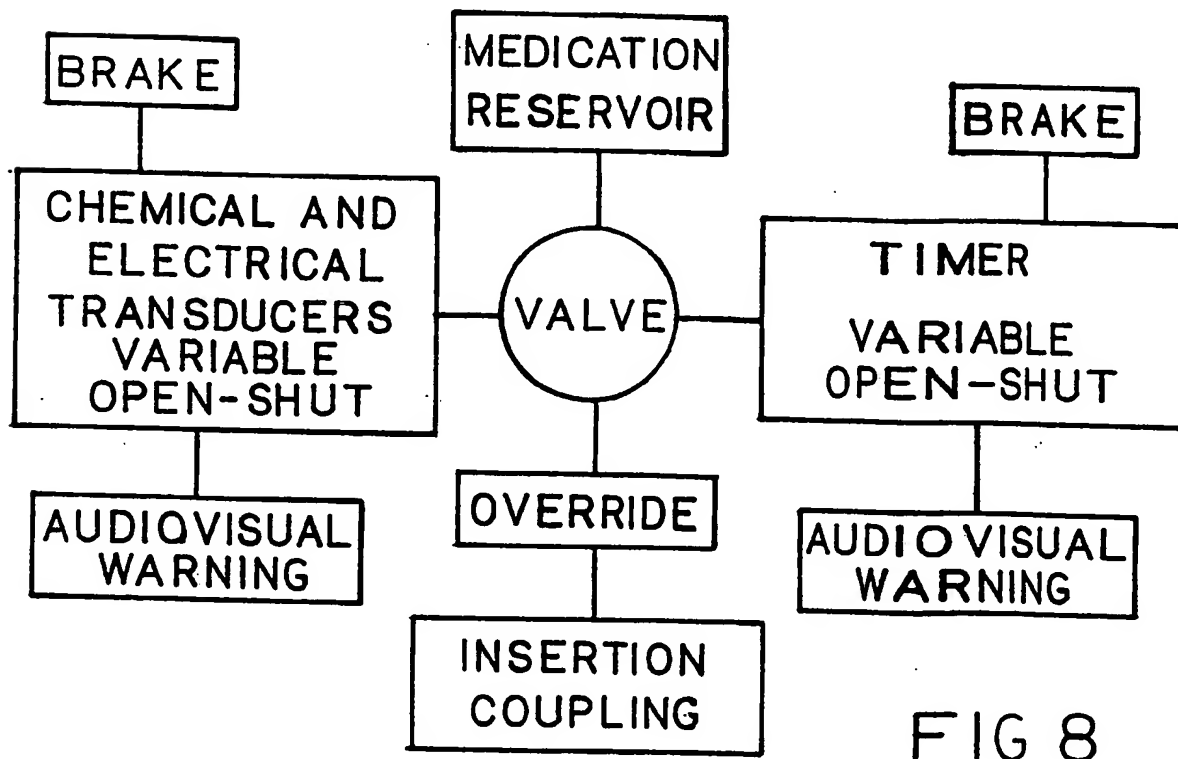
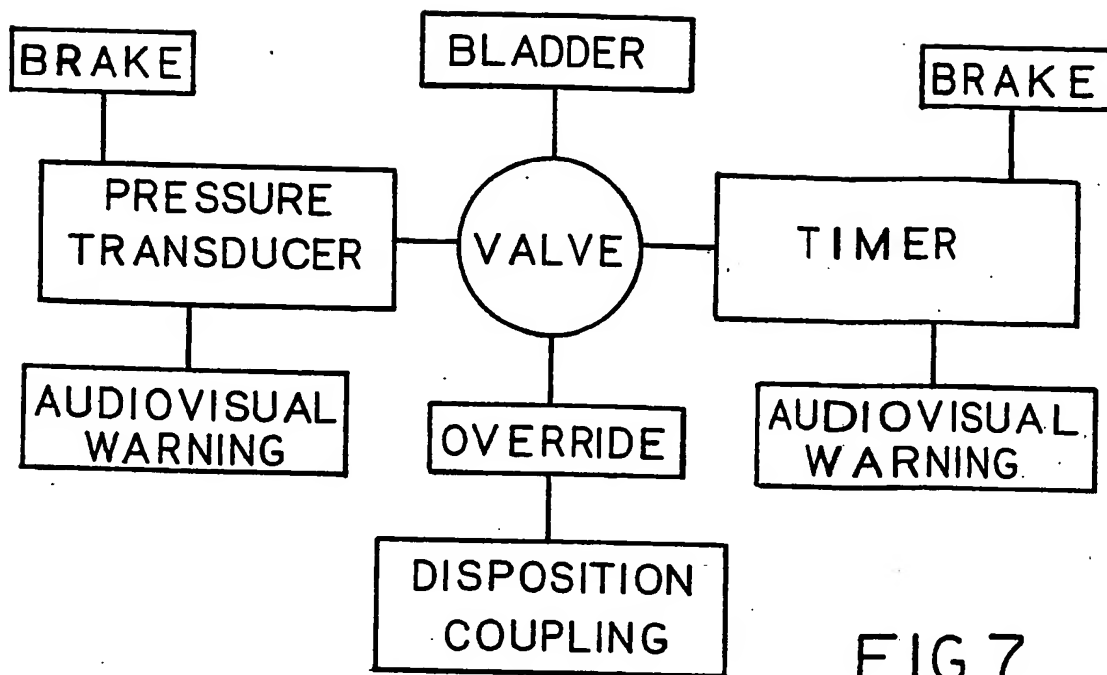


FIG 6

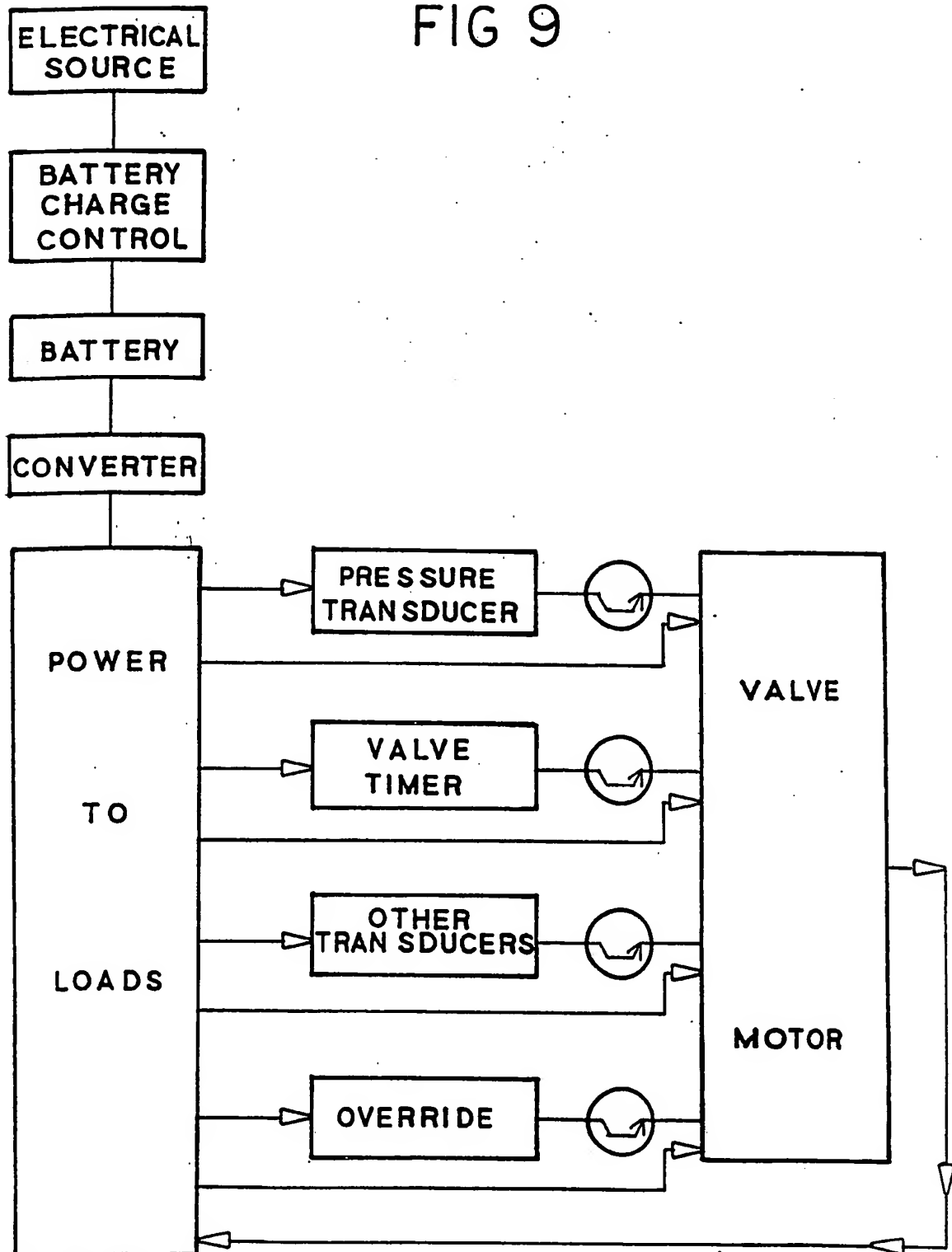


3/4



4/4

FIG 9



INTERNATIONAL SEARCH REPORT

International Application No. PCT/US89/00010

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC (4): A61M 31/00 U.S. Cl. 604/67, 250																										
II. FIELDS SEARCHED <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 25%; border-bottom: 1px solid black;">Classification System</th> <th style="border-bottom: 1px solid black;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px;">U.S.</td> <td style="padding: 5px;">604/34, 50, 65, 66, 67, 50, 245, 250</td> </tr> </table> <div style="text-align: center; border-top: 1px solid black; border-bottom: 1px solid black; margin: 5px 0;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	U.S.	604/34, 50, 65, 66, 67, 50, 245, 250																				
Classification System	Classification Symbols																									
U.S.	604/34, 50, 65, 66, 67, 50, 245, 250																									
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%; border-bottom: 1px solid black;">Category [*]</th> <th style="width: 60%; border-bottom: 1px solid black;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 30%; border-bottom: 1px solid black;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;"><u>X</u> <u>Y</u></td> <td style="padding: 5px;">US, A, 4,230,102 (EKBLADH) 28 October 1980 See the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-3,7-8,76 <u>4-6,23-53,</u> 58-68</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 4,725,269 (DANBY ET AL.) 16 February 1988, see the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">9-22,54-57, 69-75,77</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 4,073,292 (EDELMAN) 14 February 1978 See the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">9-22,54-57 69-75,77</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 3,481,334 (DISKIN ET AL) 02 December 1969, see the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">6,13,19,25, 34,43,59,74</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 1,610,622 (SHAWEKER) 14 December 1926, see the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">50-57</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">Y</td> <td style="padding: 5px;">US, A, 4,111,198 (MARX ET AL.) 05 September 1978, see the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">5,11,18,28 37,46,52, 55,62,73</td> </tr> <tr> <td style="text-align: center; vertical-align: top; padding: 5px;">A</td> <td style="padding: 5px;">US, A, 4,731,069 (KRUMME) 15 March 1988 See the entire document.</td> <td style="text-align: center; vertical-align: top; padding: 5px;">1-77</td> </tr> </table>			Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	<u>X</u> <u>Y</u>	US, A, 4,230,102 (EKBLADH) 28 October 1980 See the entire document.	1-3,7-8,76 <u>4-6,23-53,</u> 58-68	Y	US, A, 4,725,269 (DANBY ET AL.) 16 February 1988, see the entire document.	9-22,54-57, 69-75,77	Y	US, A, 4,073,292 (EDELMAN) 14 February 1978 See the entire document.	9-22,54-57 69-75,77	Y	US, A, 3,481,334 (DISKIN ET AL) 02 December 1969, see the entire document.	6,13,19,25, 34,43,59,74	Y	US, A, 1,610,622 (SHAWEKER) 14 December 1926, see the entire document.	50-57	Y	US, A, 4,111,198 (MARX ET AL.) 05 September 1978, see the entire document.	5,11,18,28 37,46,52, 55,62,73	A	US, A, 4,731,069 (KRUMME) 15 March 1988 See the entire document.	1-77
Category [*]	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³																								
<u>X</u> <u>Y</u>	US, A, 4,230,102 (EKBLADH) 28 October 1980 See the entire document.	1-3,7-8,76 <u>4-6,23-53,</u> 58-68																								
Y	US, A, 4,725,269 (DANBY ET AL.) 16 February 1988, see the entire document.	9-22,54-57, 69-75,77																								
Y	US, A, 4,073,292 (EDELMAN) 14 February 1978 See the entire document.	9-22,54-57 69-75,77																								
Y	US, A, 3,481,334 (DISKIN ET AL) 02 December 1969, see the entire document.	6,13,19,25, 34,43,59,74																								
Y	US, A, 1,610,622 (SHAWEKER) 14 December 1926, see the entire document.	50-57																								
Y	US, A, 4,111,198 (MARX ET AL.) 05 September 1978, see the entire document.	5,11,18,28 37,46,52, 55,62,73																								
A	US, A, 4,731,069 (KRUMME) 15 March 1988 See the entire document.	1-77																								
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>[*] Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																										
IV. CERTIFICATION <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black; padding: 5px;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="padding: 5px;">06 June 1989</td> <td style="text-align: center; padding: 5px;">18 JUL 1989</td> </tr> <tr> <td style="border-bottom: 1px solid black; padding: 5px;">International Searching Authority</td> <td style="border-bottom: 1px solid black; padding: 5px;">Signature of Authorized Officer</td> </tr> <tr> <td style="padding: 5px;">ISA/US</td> <td style="text-align: center; padding: 5px;"> Denise Whelton </td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	06 June 1989	18 JUL 1989	International Searching Authority	Signature of Authorized Officer	ISA/US	 Denise Whelton																
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report																									
06 June 1989	18 JUL 1989																									
International Searching Authority	Signature of Authorized Officer																									
ISA/US	 Denise Whelton																									

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

A	US, A, 4,710,166 (THOMPSON ET AL.) 01 December 1987, see the entire document.	1-77
A	US, A, 4,714,463 (ARCHIBALD ET AL.) 22 December 1987, see the entire document.	1-77
A	US, A, 4,253,456 (SCHINDLER ET AL.) 03 March 1981, see the entire document.	1-77
A	US, A, 4,355,638 (IWATSCHENKO ET AL.) 26 October 1982, see the entire document.	1-77
A	US, A, 4,504,263 (STEUER ET AL.) 12 March 1985, see the entire document.	1-77

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers because they relate to subject matter¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out¹³, specifically:

3. ☐ Claim numbers because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING²

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	US, A, 4,718,891 (LIPPS) 12 January 1988 See the entire document.	1-77
T	US, A, 4,808,161 (KAMEN) 28 February 1989 See the entire document.	1-77
T	US, A, 4,820,265 (DESATNICK ET AL.) 11 April 1989, see the entire document.	1-77